REMARKS

The claims have been amended to resolve issues raised by the Examiner. New claims have been added to specific PGE 1 compounds, including the compound used in the working examples.

Entry of the amendment is respectfully requested.

Withdrawn Claims

On page 2 of the Office Action, in paragraph 2, the Examiner indicates that new Claim 18 does not read on the elected specie, so Claim 18 and dependent Claims 3, 4, 6, 8, and 10 are withdrawn from consideration.

In response, Applicant respectfully requests that the Examiner proceed to examiner the non-elected species when the elected species is found to be allowable, in a manner like that set forth in MPEP 803.02. In this regard, Applicant notes that the Examiner indicates in paragraph 6 on page 2 of the Office Action that the scope of the search has been broadened to include 13,14-dihydro-15-keto-16,16-difluoro-PGE2, so the Examiner has proceeded to examine non-elected species to some extent.

Declaration

On page 3 of the Office Action, in paragraph 8, the Examiner indicates that the oath or declaration is defective because the provisional application for which Applicant is claiming priority is misnumbered, and thus a new oath or declaration identifying this application by application number and filing date is required.

In response, Applicant submits herewith a new Declaration referring to the provisional application number 60/420,336. Thus, Applicant submits that this issue has been resolved.

Rejection under 35 U.S.C. 112, Second Paragraph

On page 3 of the Office Action, in paragraph 10, claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

In particular, the Examiner indicates that the phrase "**general** formula" (emphasis added) renders claims 20 and 21 indefinite because the claims limit the compounds by way of limiting what constituents are included, thus conflicting with the word "general" in the phrase.

In response, Applicant has amended the claims to delete the word "general" from claims 20 and 21 (and also claim 18). Accordingly, Applicant submits that the amended claims satisfy the requirements of 35 U.S.C. 112, second paragraph, and withdrawal of this rejection is respectfully requested.

Written Description Rejection under 35 U.S.C. 112, First Paragraph

On page 4 of the Office Action, in paragraph 12, claims 1, 5, 7, 9, 11-13, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner's Position

The Examiner's position is basically that the specification as filed does not provide support for the limitation "administering to a mammalian subject in need of reduction of body weight" in amended claim 1, the limitation of administration of an effective amount of a prostaglandin compound represented by formula (I) "to reduce body weight" in new claim 20,

and the recitation of "[a] method for reducing body weight" in new claim 21. While Applicant asserts the last paragraph on page 26 of the specification provides support for these new claim limitations, the Examiner considers that the last paragraph on page 26 merely describes exemplary data depicted in Fig. 1, stating "Fig. 1 shows the changes of body weight from the pre-values in each group at 3 weeks after the initiation of the administration [of 13,14-dihydro-15-keto-16,16-difluoro-PGE1]. As shown in Fig. 1, body weight reductions were observed in all test groups while an increase was observed in the control group. The body weight of the test groups decreased in a dose dependent manner." However, the Examiner indicates that no statistical analysis of the data is provided, and the specification does not indicate whether the test subjects were obese and in need of a reduction of body weight. Thus, the Examiner considers that the data presented in Fig. 1 provides a teaching of an apparent reduction of body weight in human test subject of undisclosed weight status, at doses of 24, 48 and 72 μg of 13,14-dihydro-15-keto-16,16-difluoro-PGE1, but the present claims are much broader than the teaching of Fig. 1. Thus, the Examiner asserts that the specification fails to provide support for the full breadth of the claims as amended and newly added.

Applicant's Response

In response, Applicant respectfully disagrees with the Examiner for at least the following reasons.

With respect to the statistical analysis issue raised by the Examiner, Applicant submits that the Examiner has not provided any support for his position that a statistical analysis of the data is needed, and Applicant further submits that numerous pharmaceutical-related patents with method claims have been granted without any statistical analysis of the data therein (for

example, U.S. Patent 6,839,882 cited by the Examiner in the Office Action of December 7, 2007 is such a patent).

As to the Examiner's position that the specification does not indicate whether the test subjects were obese and in need of a reduction of body weight, Applicant submits that the present application overall is directed to treating obesity and that obese subjects are in need of a reduction of body weight, so one skilled in the art would consider that the application as a whole, including the overall disclosure and the Examples, fairly supports the claimed invention.

In regard to the application overall, Applicant submits that from the disclosure beginning at page 1, line 24 in the specification, it is readily apparent the meaning of treating obesity in this application involves reducing body weight.

Thus, Applicant submits that the present invention satisfies the written description requirement under 35 U.S.C. 112, first paragraph, and withdrawal of this rejection is respectfully requested.

Enablement Rejection under 35 U.S.C. 112, First Paragraph

On page 5 of the Office Action, in paragraph 13, claims 1, 5, 7, 9, 11-13, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the weight of obese patients, does not reasonably provide enablement for the prevention of obesity.

The Examiner's position is basically that Applicant claims a method for treating obesity or reducing body weight in a mammalian subject in need of treatment for obesity by administering an effective amount of prostaglandin compounds defined by broad formula (I), but the specification defines the term "treatment" to include "any means of control such as

prevention, care, relief of the condition, attenuation of the condition and arrest of progression" (see page 24, lines 20-22), and the physiological or pharmaceutical activity of preventing obesity, particularly with regard to the multitude of factors which influence the development of obesity, is an unpredictable art. Thus, the Examiner does not understand how one skilled in the art can reasonably expect that the instant compound can be administered in order to have the "preventive" effect. In this regard, the Examiner indicates that the PTO maintains a very high standard of enablement for claims drawn to methods of prevention.

In response, Applicant has amended the independent claims to recite that the treating comprises care, relief, attenuation, or arrest of progression of obesity, based on the disclosure at, e.g., page 24, lines 20-22 in the specification.

Thus, Applicant submits that the present invention satisfies the enablement requirement under 35 U.S.C. 112, first paragraph, and withdrawal of this rejection is respectfully requested.

Anticipation Rejection

On page 9 of the Office Action, in paragraph 15, claims 1, 5, 7, 9, 12, 13, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueno et al. (U.S. Patent No. 5,234,954).

The Examiner's Position

The Examiner's position is basically that Ueno et al. teach a method for the treatment of hyperlipidemia comprising administration of a 15-keto-prostaglandin compound, including a 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E compound, and Ueno et al. teach the disclosed PGE compounds decrease blood levels of triglyceride, cholesterol or phospholipid (irrespective of cause, e.g., disease, drug or food) by promoting release into the intestine or release with feces. Further, the Examiner indicates that Ueno et al. teach the method useful for

reducing said blood lipids in obese individuals. The Examiner indicates that treating hyperlipidemia in obese individuals with the same PGE compounds at the same doses as instantly claimed, as disclosed by Ueno et al., would naturally produce the same reduction of body weight as is instantly claimed. In support of his inherency-based position, the Examiner cites *In re Best, In re Fitzgerald, Schering Corp. v. Geneva Pharm. Inc., Toro Co. v. Deere & Co.*, and *SmithKline Beecham Corp. v. Apotex Corp.*

Applicant's Response

Initially, Applicant notes with appreciation that the Examiner has not included claim 11 in this rejection, so the Examiner has recognized that the particular compounds recited therein are not taught by the '954 patent.

Further, Applicant notes that all the case law cited by the Examiner is from MPEP 2112 and is directed to various aspects of inherency. However, MPEP 2112 also states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not

sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). ...

"In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

See MPEP 2112 IV.

Thus, for the Examiner's inherency position to be applicable, the presently claimed method involving reduction of body weight must necessarily result from the '954 patent. However, as can be seen from the disclosure at col. 18, Table 1 and lines 39-40 in the '954 patent, almost no influence was observed in respect to body weight in Test Example 1 (the only test example which discusses body weight). Accordingly, Applicant submits that the Examiner has not shown that the presently claimed method necessarily results from the '954 patent, and thus the rejection based on inherency is improper.

Moreover, Applicant submits that with respect to method of treatment claims in particular, the relevant case law includes *Jansen v. Rexall Sundown, Inc.*, 342.F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003), wherein in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. See MPEP 2111.02 II. Thus, Applicant submits that the present claims should be properly interpreted to mean that the recited compound must be administered to a subject with a recognized need to reduce body weight and for the purpose of

reducing the body weight of that subject. Applicant submits that the '954 patent does not disclose or suggest administering the recited compound to a subject with a recognized need to reduce body weight and for the purpose of reducing the body weight of that subject. Accordingly, Applicant submits that the present invention is not anticipated by (or obvious over) the '954 patent.

Thus, Applicant submits that this rejection over the '954 patent has been overcome, and withdrawal of this rejection is respectfully requested.

Obviousness Rejection

On page 11 of the Office Action, in paragraph 17, claims 1, 5, 7, 9, 11, 12, 13, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (U.S. Patent No. 5,234,954), as evidenced by Dietz (Pediatrics, Vol. 101, Issue 3 (Supplement), pages 518-525).

The Examiner's Position

The Examiner's position is basically that Dietz discloses that hyperlipidemia is common in obese individuals, and it would have been obvious to utilize the teachings of Ueno et al. to treat a common symptom of obesity, hyperlipidemia, by the administration of a 15-ketoprostaglandin compound, including a 13,14-dihydro-15-deto-16,16-difluoroprostaglandin E compound. Further, Ueno et al. teach both the PGE1 and PGE2 forms of the 15-keto prostaglandin compounds are useful in the disclosed methods. While they do not specifically disclose the PGE1 of the instantly elected 15-keto prostaglandin (they disclose the PGE2 form), it would have been obvious to also evaluate the effectiveness of PGE1 form of the 15-keto prostaglandins, since Ueno et al. teach both forms of the 15-keto prostaglandins to be useful.

Therefore, the Examiner considers that the invention as a whole is prima facie obvious, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's Response

In response, Applicant submits initially that the cited art does not disclose or suggest administering the recited compound to a subject with a recognized need to reduce body weight and for the purpose of reducing the body weight of that subject. Rather, the cited art is simply directed to treating hyperlipidemia. Applicant submits that hyperlipidemia is a disease diagnosed by higher serum lipid and is not necessarily associated with obesity. Further, Applicant submits that hyperlipidemia is not a condition commonly observed in obesity patients.

In addition, Applicant submits that there is a discrepancy among the Examiner's allegations. On page 11 of the Office Action, the Examiner alleges that hyperlipidemia is common in obese individuals and that it would have been obvious to treat hyperlipidemia by a 15-keto PG compound based on US 5,234,954. On the other hand, on page 6, in item (3), and on page 7, in item (5), the Examiner alleges that "there are many factors that influence weight gain, including: genetic and environmental factors, physical inactivity, alcohol consumption, socioeconomics, menopause in women, stress, polycystic ovary syndrome, pharmaceuticals, and smoking cessation" and that "the physiological or pharmaceutical activity of preventing obesity, particularly with regard to the multitude of factors which influence the development obesity, is an unpredictable art". Thus, Applicant submits that the Examiner's position with respect to this obviousness rejection is inconsistent with the Examiner's position elsewhere in the Office Action.

Moreover, Applicant submits that the disclosure at col. 18, Table 1 and lines 39-40 in the '954 patent indicates that almost no influence was observed in respect to body weight in Test

Example 1 (the only test example which discusses body weight). Accordingly, Applicant submits that the claimed method involving reducing body weight would not have been obvious from the cited art.

In addition, Applicant has added an independent claim reciting a method of treating obesity in a mammalian subject which comprises administering to a mammalian subject in need of treatment for obesity an effective amount of 13,14-dihydro-15-keto-16,16-difluoro-PGE_1, since the cited art does not specifically teach or suggest that compound (Applicant notes that this claim does not include a recitation directed to reduction of body weight, so that the issues raised by the Examiner with respect to that recitation do not apply).

In this regard, Applicant submits that in view of the election of species requirement in the Office Action of May 2, 2007, the species within the scope of the broadly claimed invention should be considered patentably distinct from each other, and Applicant submits that the elected species is patentably distinct from any other species of the broadly claimed present invention that the Examiner might consider as being disclosed in the cited art, so at least the newly added claim, which is specifically directed to the elected species, is patentable over the cited art. Similarly, Applicant submits that claim 11 should be allowable over the cited art on the same basis (i.e., that it is directed to species which are patentably distinct from any other species of the broadly claimed present invention that the Examiner might consider as being disclosed in the cited art).

Thus, Applicant submits that the present invention is not obvious over the cited art, and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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